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Act, and any active ingredient or device, or to package, repackage, label, relabel, or otherwise change the container of any pesticide or device.

Producer means any person, as defined by the Act, who produces any pesticide, active ingredient, or device (including packaging, repackaging, labeling and relabeling).

Refillable container means a container that is intended to be filled with pesticide more than once for sale or distribution.

Refiller means a person who engages in the activity of repackaging pesticide product into refillable containers. This could include a registrant or a person operating under contract to a registrant.

Refilling establishment means an establishment where the activity of repackaging pesticide product into refillable containers occurs.

Repackage means, for the purposes of this part, to transfer a pesticide formulation from one container to another without a change in the composition of the formulation, the labeling content, or the product's EPA registration number, for sale or distribution.

Rinsate means the liquid resulting from the rinsing of the interior of any equipment or container that has come in direct contact with any pesticide.

Runoff means surface water leaving the target site.

Secondary containment unit means any structure, including rigid diking, that is designed and constructed to intercept and contain pesticide spills and leaks and to prevent runoff and leaching from stationary pesticide containers.

Stationary pesticide container means a refillable container that is fixed at a single facility or establishment or, if not fixed, remains at the facility or establishment for at least 30 consecutive days, and that holds pesticide during the entire time.

Suspension concentrate means a stable suspension of solid particulate active ingredients in a liquid intended for dilution with water before use.

Tamper-evident device means a device which can be visually inspected to determine if a container has been opened.

Transport vehicle means a cargo-carrying vehicle such as an automobile,

van, tractor, truck, semitrailer, tank car or rail car used for the transportation of cargo by any mode.

Washwater means the liquid resulting from the rinsing of the exterior of any equipment or containers that have or may have come in direct contact with any pesticide or system maintenance compound, such as oil or antifreeze.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64224, Oct. 29, 2008]

§§ 165.4-165.19 [Reserved]

Subpart B—Nonrefillable Container Standards: Container Design and Residue Removal

§ 165.20 General provisions.

(a) What is the purpose of the regulations in this subpart? The regulations in this subpart establish design and construction requirements for nonrefillable containers used for the distribution or sale of some pesticide products.

(b) Do I have to comply with the regulations in this subpart? You must comply with the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in nonrefillable containers. If your pesticide product is subject to the regulations in this subpart as set out in §165.23, your pesticide product must be distributed or sold in a nonrefillable container that meets the standards of these regulations

(c) When do I have to comply? Any pesticide product packaged in a nonrefillable container and released for shipment by you after August 16, 2009 must be packaged in a nonrefillable container that complies with the regulations of this subpart.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§ 165.23 Scope of pesticide products included.

(a) Are manufacturing use products subject to the regulations in this subpart? No, the regulations in this subpart do not apply to manufacturing use products, as defined in §158.153(h) of this chapter.

(b) Are plant-incorporated protectants subject to the regulations in this subpart? No, the regulations in this subpart do

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not apply to plant-incorporated protectants, as defined in §174.3 of this chapter.

- (c) Which antimicrobial pesticide products are not subject to the regulations in this subpart? The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:
- (1) The pesticide product meets one of the following two criteria:
- (i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or
- (ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and
- (B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.
- (2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.
- (3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.
- (4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment according to the provisions of paragraph (d) of this section.
- (d) How will EPA determine if an antimicrobial pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?

- (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:
- (i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.
- (ii) The information, data or other evidence is reliable and factual.
- (iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.
- (iv) Complying with the container regulations could reasonably be expected to eliminate the problem.
- (2) If EPA determines that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the nonrefillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in nonrefillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the nonrefillable container regulations within the time frames established by EPA in the rule or in its notification.
- (e) What other pesticide products are subject to the regulations in this subpart? (1) Except for manufacturing use products, plant-incorporated protectants,

and antimicrobial products that are exempt under paragraph (c) of this section, all of the regulations in this subpart apply to a pesticide product if it satisfies at least one of the following criteria:

- (i) The pesticide product meets the criteria of Toxicity Category I as set out in §156.62 of this chapter.
- (ii) The pesticide product meets the criteria of Toxicity Category II as set out in §156.62 of this chapter.
- (iii) The pesticide product is classified for restricted use as set out in §§ 152.160 152.175 of this chapter.
- (2) Except for manufacturing use products, plant-incorporated protectants, antimicrobial products that are exempt under (c) of this section, and other pesticide products that are regulated under paragraph (e)(1) of this section, a pesticide product must be packaged in compliance with 49 CFR 173.24. If the pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the Department of Transportation requires it to be packaged according to 49 CFR parts 171–180.
- (f) What does "pesticide product" or "pesticide" mean in the rest of this subpart? In §§165.25 through 165.27, the term "pesticide product" or "pesticide" refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (e) of this section.

[71 FR 47422, Aug. 16, 2006, as amended at 73 FR 64225, Oct. 29, 2008]

§ 165.25 Nonrefillable container standards.

(a) What Department of Transportation (DOT) standards do my nonrefillable containers have to meet under this part if my pesticide product is not a DOT hazardous material? A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR 173.4, 173.5, 173.6, 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material, or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.

- (b) What DOT standards do my non-refillable containers have to meet under this part if my pesticide product is a DOT hazardous material? (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B.
- (2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a nonrefillable container that, if portable, is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180 or, if subject to a special permit, according to the applicable requirements of 49 CFR part 107 subpart B. The requirements in this paragraph apply to the pesticide product as it is packaged for transportation in commerce.
- (c) What will EPA do if DOT proposes to change any of the cross-referenced regulations? If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the FEDERAL REGISTER. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such revision will correspond with revised DOT regulations.
- (d) What standards for closures do my nonrefillable containers have to meet? If your nonrefillable container is a rigid container with a capacity equal to or greater than 3.0 liters (0.79 gallons), if the container is not an aerosol container or a pressurized container, and if the container is used to distribute or sell a liquid agricultural pesticide, each nonrefillable container must have at least one of the following standard closures:
- (1) Bung, 2 inch pipe size (2.375 inches in diameter), external threading, 11.5